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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,798

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Tadashi Okamoto

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FITZPATRICK CELLA HARPER & SCINTO  
1290 Avenue of the Americas  
NEW YORK, NY 10104-3800

EXAMINER

STAPLES, MARK

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

01/05/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,798	<b>Applicant(s)</b> OKAMOTO, TADASHI	
	<b>Examiner</b> MARK STAPLES	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 11-15, 17, 18 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-10, 16, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                 |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application       |
| Paper No(s)/Mail Date <u>12/06/2006, 10/26/2007, &amp; 07/15/2008</u> .                | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> . |

### DETAILED ACTION

1. Applicant's election with traverse of claims 1-20 of Group 1 as noted by further election species within Group I the reply filed on 10/19/2009 is acknowledged. The traversal is on the ground(s) that that there the burden would be normal to examine all of the claims together. This is not found persuasive because the groups of inventions are not so linked as to form a single general inventive concept. There is no special technical feature linking the groups of inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/19/2009.

2. Applicant's election without traverse of Species (1) in the reply filed on 10/19/2009 is acknowledged.

Claims 2-4 and 11-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/19/2009.

In summary, claims 1, 5-10, 16, 19, and 20 of Group I as filed on 09/06/2006 will be fully examined for patentability.

***Oath/Declaration***

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It is directed to PCT/JP2005/0004881 and does not reflect the amendments of the claims in the PCT application.

***Priority***

4. Receipt is acknowledged of papers which is a copy PCT/JP05/04881 03/14/2005 application submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

5. Receipt is acknowledged of papers which is a certified copy Japan Number 2004-070986 application submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The copy is not in English.

***Sequence Rules Compliance***

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence

Art Unit: 1637

And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given time of reply to this office action within which to comply with the sequence rules, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in **abandonment** of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Pages 26 and 41 respectively contain sequences without SEQ ID NOs. If these sequences are included in the sequence listing provide by Applicant, the specification should be amended to include the SEQ ID NOs. If these sequences were not included in the sequence listing filed 05/29/2007, Applicant should provide a substitute sequence listing and a CRF that include those sequences.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1637

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 5-7, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (US 2001/0036632 published 2001).

Regarding claim 1, Yu et al. teach methods of detecting a nucleic acids (entire publication), comprising the steps of:

(1) preparing a single-stranded nucleic acid having plural partial and sequential base sequences to be detected (A-strand) and a single-stranded nucleic acid having a base sequence complementary to a base sequence of the A-strand (B-strand) (see any one of the single strands of Gene A, B, or C and multiple primers to each single strand in Figure 1 and noting the complements bind to these primers in step 1B);

(2) preparing nucleic acids as primers each having one of the plural base sequences to be detected, immobilizing the respective primers independently in separate regions on a substrate, and preparing a primer array in which the respective base sequences to be detected are distributed in the primer-immobilized regions (see Figure 1 steps 1A and 1B and claim 1);

(3) preparing a nucleic acid having a sequence complementary to a partial and sequential base sequence within the region between a 3'-end of the A-strand and the base sequence to be detected which is located nearest the 3'-end as a primer for elongating the B-strand (see Figure 1 step 1B and claim 1);

(4) performing PCR reactions using the A-strand and B-strand as templates, and using the primers immobilized on the substrate, and the primer for elongating the B-

Art Unit: 1637

strand (see Figure 1 step 1C, see section 5. *PCR Reactions* beginning at paragraph 0093, and see claim 1);

(5) forming a hybridized product of a nucleic acid corresponding to the A-strand which has been elongated and amplified as a result of the PCR reactions and bound to the substrate and a nucleic acid corresponding to the B-strand which has been elongated and amplified and has not bound to the substrate (see successive steps 1C through 1E of Figure 1); and

6) detecting the base sequence to be detected by detecting the hybridized product in the respective primer-immobilized regions in the array (note the labels for detection in Figure 1 and see claim 1).

Regarding claim 5, Yu et al. teach washing after the PCR reaction (see paragraph 0063, especially the 3<sup>rd</sup> sentence).

Regarding claims 6 and 7, Yu et al. teach fluorescent CY3 or CY5 labeled primers for synthesis of the new strands (see paragraph 0066 and also see paragraph 0006 for labeled probes).

Regarding claim 16, Yu et al. teach quantitative detection (see paragraph 0007).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1637

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8-10, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. as applied to claim 1 above, and further in view of Wang (2000).

Yu et al. teach as noted above.

Regarding claims 9, Yu et al. teach fluorescence detection and teach detection with intercalators and/or minor groove binders (see paragraph 0083) which inherently interact with double stranded nucleic acid, but do not specifically teach fluorescent intercalators.

Regarding claims 8-10, Schmidt et al. teach fluorescently labeled probes hybridized to nucleic acids bound to arrays of distinct wells on a microplate and also teach fluorescent intercalators which bind to double stranded nucleic acids (see column 4 lines 1 to 8 and see *Intercalating Dyes* beginning at column 4 line 9) which can be detected with confocal microscopy (see column 4 line 50).

Regarding claims 19 and 20, Schmidt et al. teaches measurements in real time, that is intermittently (see column 3 lines 40-67), and where the nucleic acid detection are performed in the same well/container of a micro-plate (see column 4 lines 1 to 8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Yu et al. by using confocal microscopy to detect fluorescent intercalators on arrays as suggested by



Art Unit: 1637

Schmidt et al. with a reasonable expectation of success. The motivation to do so is provided by Schmidt et al. who teach that their methods result in improved detection of functional antisense agents and can simultaneously measure the kinetics of complementary nucleic acid strand hybridizations (see column 1 lines 1-53). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Conclusion**

11. No claim is free of the prior art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Staples/  
Primary Examiner, Art Unit 1637  
January 1, 2010